

PATENT Attorney Docket No. 056291-5192

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re	Application of: ANDERBER) Confirmation No.: 4755	
Appli	cation No.: 10/520,939	₺.) Group Art Unit: 1645
Filed:	January 12, 2005		Examiner: Unassigned
For:	COMBINATION OF AN IBAT INHIBITOR AND A METAL SALT FOR THE TREATMENT OF DIARRHOEA)))

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Window, Mail Stop Amendment
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Citation of Related U.S. Patent Applications

The Examiner's attention is directed to the following related co-pending U.S. patent applications:

Inventor	U.S. Serial No.	U.S. Patent No.	PCT Publication No.
	Filing Date	Issue Date	PCT Publication Date
Starke et al.	10/220,877	6,906,058	WO 01/66533
	March 5, 2001	June 14, 2005	September 13, 2001
Starke et al.	10/399,336		WO 02/32428
	September 16, 2003		April 25, 2002
Starke et al.	10/451,262		WO 02/50051
	June 20, 2003		June 27, 2002
Starke et al.	10/488,540		WO 03/020710
	July 23, 2004		March 13, 2003
Starke et al.	10/489,009		WO 03/022825
	October 8, 2004		March 20, 2003
Starke et al.	10/489,010		WO 03/022830
•	October 21, 2004		March 20, 2003
Starke et al.	10/488,870		WO 03/022286
	October 7, 2004		March 20, 2003
Lindqvist	10/502,355		WO 03/061663
	February 4, 2005		July 31, 2003
tarke et al.	10/511,984		WO 03/091232
	October 21, 2004		November 6, 2003

Inventor	U.S. Serial No. Filing Date	U.S. Patent No. Issue Date	PCT Publication No. PCT Publication Date
Starke et al.	10/518,010		WO 03/106482
	December 14, 2004		December 24, 2003

A copy of the specification and claims for each application, in the form of the published PCT application from which such application was filed is being filed herewith.

<u>PLEASE DO NOT PRINT</u> the above information on the patent resulting from the subject application.

Consideration of each listed application is earnestly solicited since unpublished patent applications are contemplated as IDS material; see the exception in Rule 98(a)(2)(iii) and note the penultimate sentence of MPEP 609.

Further, in keeping with MPEP 609, Subsec. C(2), 2nd para., line 10 to end of the paragraph (especially note lines 18-25) PLEASE RETURN A COPY OF THIS LETTER with the Examiner's initials adjacent each above listing so that applicant will know that each listed application has been considered as required by PTO policy.

Citation of Documents

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants petition the Examiner to consider this Supplemental Information Disclosure Statement and documents listed on the attached Form PTO-1449. To the best of the undersigned's knowledge, this Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced Application. Accordingly, Applicants do not believe a fee is due for filing this Supplemental Information Disclosure Statement.

With the exception of a published U.S. Application, copies of the listed documents are attached. Applicants respectfully request that the Examiner initial and return the Form PTO-1449, indicating that the information has been considered and made of record herein.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If it should be determined that the listed documents constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate

status of such document.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R.

§1.136(a)(3).

Respectfully Submitted.

Morgan Lewis & Bockins

Date:

December 30, 2005

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Attorney Docket No. Application No. INFORMATION DISCLOSURE (CITEATION 056291-5192 10/520,939 1288 (Use several sheets if necessary) Applicants: ANDERBERG et al. PTO Form 1449 JAN 0 6 2006 Filing Date: January 12, 2005 Group Art Unit: 1645 U.S. PATENT DOCUMENTS Initial Document No. Date Name Class Sub-Class Filing Date US 2002/142054 10/3/2002 Marlett et al. 424 738 September 10, 2001 FOREIGN PATENT DOCUMENTS Document No. Date Country Class Sub-Class Translation 2. DE 19825804 12/16/1999 DE EP 0372542 3. 6/13/1990 EP 4. EP 0864582 9/16/1998 EP GB 2,262,888 5. 7/7/1993 GB 6. WO 93/16055 8/19/1993 WIPO WO 94/18183 7. 8/18/1994 **WIPO** 8. WO 94/18184 8/18/1994 WIPO WO 96/05188 9. 2/22/1996 **WIPO** 10. WO 96/08484 3/21/1996 **WIPO** 11. WO 96/16051 5/30/1996 **WIPO** 12. WO 97/33882 9/18/1997 WIPO 13. WO 98/38182 9/3/1998 WIPO 14. WO 98/40375 9/17/1998 WIPO 15. WO 99/01149 1/14/1999 **WIPO** WO 99/32478 16. 7/1/1999 **WIPO** WO 99/35135 17. 7/15/1999 **WIPO** WO 99/64409 18. 12/16/1999 **WIPO** WO 99/64410 19. 12/16/1999 WIPO 20. WO 00/01687 1/13/2000 WIPO 21. WO 00/38725 7/6/2000 **WIPO** 22. WO 00/38726 7/6/2000 **WIPO** 23. WO 00/38727 7/6/2000 WIPO 24. WO 00/38728 7/6/2000 **WIPO** 25. WO 00/38729 7/6/2000 WIPO 26. WO 00/47568 8/17/2000 **WIPO** 27. WO 00/61568 10/19/2000 **WIPO** 28. WO 00/62810 10/26/2000 **WIPO** 29. WO 01/60807 8/23/2001 WIPO 30. WO 01/66533 9/13/2001 WIPO 31. WO 01/68096 9/20/2001 **WIPO** 32. WO 01/68637 9/20/2001 WIPO 33. WO 02/08211 1/31/2002 WIPO OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.) Examiner Date Considered Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Attorney Docket No. Application No. INFORMATION DISCLOSURE TATION 056291-5192 10/520,939 (Use several sheets if necessary) Applicants: ANDERBERG et al. JAN 06 2006 PTO Form 1449 Filing Date: January 12, 2005 Group Art Unit: 1645 **U.S. PATENT DOCUMENTS** Initial Document No. Date Name Class Sub-Class Filing Date FOREIGN PATENT DOCUMENTS Document No. Country Class Sub-Class Translation 34. WO 02/32428 4/25/2002 WIPO 35. WO 02/50051 6/27/2002 WIPO WO 02/53548 36. 7/11/2002 **WIPO** Y (Abstract) 37. WO 03/020710 3/13/2003 WIPO 38. WO 03/022286 3/20/2003 WIPO 39. WO 03/022825 3/20/2003 **WIPO** 40. WO 03/022830 3/20/2003 WIPO 41. WO 03/061663 7/31/2003 WIPO 42. WO 03/091232 11/6/2003 WIPO 43. WO 03/106482 12/24/2003 WIPO WO 2004/006899 1/22/2004 WIPO 45. WO 2004/076430 9/10/2004 WIPO WO 2004/089350 10/21/2004 WIPO OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.) Govers et al., (1994) "Characterization of the adsorption of conjugated and unconjugated bile acids to insoluble, amorphous calcium phosphate" Journal of Lipid Research, 35(5): 741-748 Higaki et al., (1998) "Inhibition of Ileal Na[†]/Bile Acid Cotransporter by S-8921 Reduces Serum Cholesterol and Prevents Atherosclerosis in Rabbits" Ateriosclerosis, Thrombosis, and Vascular Biology 18(8): 1304-1311 Ishibashi et al., (1993) "Hypercholesterolemia in low density lipoprotein receptor knockout mice and its reversal by adenovirus-mediated gene delivery" Journal of Clinical Investigation 92(2): 883-893 Lewis et al., (1995) "Effects of 2164U90 on ileal bile acid absorption and serum cholesterol in rats and mice" Journal of Lipid Research, 36(5): 1098-1105 Plump et al., (1992) "Severe hypercholesterolemia and atherosclerosis in apolipoprotein E-deficient mice created by homologous recombination in ES cells" Cell 71(2):343-353 52. Schiller (2001) "The therapy of constipation" Alimentary Pharmacology and Therapeutics 15(6): 749-763 Sprong et al., (2002) "Dietary Calcium Phosphate Promotes Listeria monocytogenes Colonization and Translocation in Rats Fed Diets Containing Corn Oil but Not Milk Fat" J. Nutrition (US) 132(6): 1269-1274 Van Tilburg et al., (1989) "Na+-dependent bile acid transport in the ileum: The balance between diarrhea and 54. constipation" Gastroenterology 98(1): 25-32 Welberg et al., (1991) "Calcium and the prevention of colon cancer" Scandinavian J. Gastroenterology Suppl Norway 188: 52-59 Examiner Date Considered Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.